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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/383,789	08/26/99	HUGHES B	X-12013

EXAMINER
LUKTON,D

ART UNIT	PAPER NUMBER
1653	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/383,789	Hughes
Examiner	**Group Art Unit**
David Lukton	1653

☒ Responsive to communication(s) filed on *Dec 11, 2000*

☐ This action is **FINAL.**

☐ *Since this application is in condition for allowance except for formal matters,* **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *19, 23, 33, and 44-69* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *19, 23, 33, and 44-69* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *7*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Pursuant to the directives of paper No. 8 (filed 12/11/00), claims 1-15, 18, 21, 22, 24-32, 34-43 have been cancelled, and claims 44-69 have added. Claims 19, 23, 33, 44-69 are pending.

Applicants' arguments filed 12/11/00 have been considered and found persuasive in part. The previously imposed §102 rejections are withdrawn.

*

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures. A sequence listing has been submitted, but contains errors.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have shown that Val^8-GLP-1 can be administered to the lungs, and that certain antigenic determinants of the peptide appears in serum. However, the immunoassay which applicants are endeavoring to employ to ascertain serum concentration does not establish that the intact peptide appears in serum. The antibodies will recognize fragments of the peptide; it may well not survive long enough to reach the blood intact. This matter is discussed to some degree in Deacon (*Diabetologia* **41**, 271, 1998). For example, it is stated (page 273, col 2 last paragraph) that the immunoassay measures both intact and N-terminally degraded peptide.

Accordingly, the question arises as to whether Val^8-GLP-1 exhibits any particular physiological effect at all when administered to the lung. There is no evidence that the peptide is in fact "useful" when delivered in this way. There is no reason to expect that merely because fragments of an untested peptide can appear in serum, that a diabetic or hyperglycemic patient would derive any benefit at all from the pulmonary administration. It is suggested that applicants cancel the claims at issue.

*

Claims 19, 23, 33, 44-69 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 19, 23, 33 recite the term "effective dose", thus rendering the claims indefinite as to the objective(s) of the efficacy.

- Claim 19 is indefinite as to the process step(s) intended. What is the endpoint...is it sufficient to administer 1 picogram of the peptide for a period of 1 nanosecond, and if so, how does the practioner know that the desired outcome had been achieved...?

- In claim 51, the term "MMAD" should be defined.

- Claim 51 recites the phrase "less than about 10 microns". This renders the claim indefinite. The issue here is, which term dominates, the "about", or the "less than"...? Would a size of e.g., 10.8 microns be included? according to one interpretation, it would be encompassed, but according to another interpretation, it would not. It is suggested that applicants delete the term "about" from claim 51. However, if desired, another claim could be added which recites "about 10 microns". This would be acceptable as long as the "about" were not preceded by "less than". The same issue applies to claim 54 ("at least about 10%").

- Claim 55 recites the phrase "capable of depositing", thus rendering the claim indefinite as to whether the deposition takes place or not. The same issue applies to claims 58 and 64.

- Each of claims 61-63 and 66-69 recite "**an** actuation ..administers". How many different "actuations" are there? It would appear that the indefinite article ("an") can be eliminated.

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The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of

assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 19, 23, 33, 44-69 are rejected under 35 U.S.C. §103 as being unpatentable over Drucker (USP 5846937) in view of Galloway (USP 5705483); or Smith (USP 5908830) in view of Galloway; or Knudsen (WO 98/20895) in view of Galloway; or Gelfand (EP 0,619,322) in view of Galloway; or Kirk (WO 93/18785) in view of Galloway.

As indicated previously, Smith teaches (col 9, line 14 and col 19, line 53) the use of a GLP-1 agonist which can be adminstered (col 11, line 58) by pulmonary means. Drucker teaches (col 8, line 50; col 9, line 31) administration of one or more GLP analogs by pulmonary means. Knudsen teaches (p. 8, line 25) admininstration of GLP peptides by pulmonary means. Gelfand teaches (p. 4, line 32) administration of GLP by pulmonary means. Kirk (WO 93/18785) teaches nasal administration of GLP peptides. None of these teach the specific GLP peptide to which the instant claims are drawn.

Galloway ('483) teaches (col 5, line 21) that Val^8-GLP-1 resists the proteolytic action of DPP-IV. Accordingly, it would have been obvious to one of ordinary skill to adminster Val^8-GLP-1 to a patient by pulmonary means.

The claims are thus rendered obvious.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800